IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

UNITED STATES OF AMERICA,

Plaintiff,

v.

TRUMAN J. BERST, an individual d/b/a ALTERNATIVE HEALTH & HERBS REMEDIES,

Defendant.

Case No. 6:11-cv-06370-TC

ORDER OF SUMMARY JUDGMENT AND PERMANENT INJUNCTION

The Court, having considered Plaintiff's Motion for Summary Judgment and supporting documents, Defendant's opposition thereto, and the entire record in this case; having found that Defendant Truman J. Berst, doing business as Alternative Health & Herbs Remedies, violates the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 331(a), by introducing and

causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, products that are unapproved new drugs, in violation of 21 U.S.C. § 331(d), and misbranded drugs, in violation of 21 U.S.C. § 331(a); and having found that Defendant, unless restrained by Order of this Court, will continue to violate the Act.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. Plaintiff's Motion for Summary Judgment is granted.

2. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

3. The Complaint for Permanent Injunction states a cause of action against Defendant under the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

4. Defendant violates the Act, 21 U.S.C. § 331(d), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

5. Defendant violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce articles of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

6. Upon entry of this Decree, Defendant and each and all of his directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from introducing or

delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce any product unless and until:

a. An approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(a) or (j) is effective with respect to the product; or

b. An effective investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

c. For any product that purports to be a drug that conforms to the requirements of any of the FDA OTC monographs, 21 C.F.R. Part 330:

i. Defendant retains, at Defendant's expense, an independent person or persons (the "monograph expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendant or his immediate family, who by reason of background, experience, education, and training is qualified to review the labeling of Defendant's OTC drugs to determine whether such products comply with the applicable OTC drug monograph and other labeling requirements of the Act and FDA regulations. Defendant shall notify FDA in writing of the identity and qualifications of the monograph expert as soon as they retain such expert;

ii. The monograph expert performs a comprehensive review of the OTC drug's proposed labeling to determine whether the product strictly conforms to an applicable FDA OTC monographs and all labeling requirements, including 21 C.F.R. Part 201, and that the OTC drug is not otherwise misbranded;

iii. The monograph expert certifies in writing to FDA that (a) he or she has reviewed the OTC drug and its labeling; (b) the OTC drug's labeling conforms to the requirements of an OTC drug monograph and all applicable labeling requirements, including

21 C.F.R. Part 201; and (c) the OTC drug is not otherwise misbranded. As part of this certification the monograph expert shall include a full and complete detailed report of the results of his or her labeling review, including references to the FDA OTC monograph and labeling regulations addressed in the process of conducting the labeling review;

iv. Defendant has provided to FDA any additional information requested by FDA after FDA's review of the monograph expert's certification pursuant to subparagraph 5(c)(iii); and

v. FDA notifies Defendant in writing that Defendant appears to be in compliance with the requirements set forth in subparagraphs 5(c)(i-iv). In no circumstance may FDA's silence be construed as a substitute for written notification; or

d. Defendant has removed all claims from Defendant's product labels, labeling, promotional materials, websites owned or controlled by or related to Defendant, and in any other media that cause that product to be a drug within the meaning of the Act, and/or contain health claims that are not authorized by 21 C.F.R. §§ 101.72-101.83 by a letter of enforcement discretion from FDA; and

e. Defendant retains an independent person or persons (the "labeling expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendant or his immediate family, who by reason of background, experience, education, and training is qualified to assess Defendant's compliance with the Act, to review the claims Defendant makes for all of his products on his product labels, labeling, promotional material, and any internet websites owned or controlled by or related to Defendant including, but not limited to, www.healthherbs.com. At the conclusion of the labeling expert's review, the labeling expert shall prepare a written report analyzing whether Defendant is operating in

compliance with the Act and in particular, certify whether Defendant has omitted all claims from his product labels, labeling, promotional materials, websites owned or controlled by or related to Defendant and in any other media, that make any of his products drugs within the meaning of the Act, 21 U.S.C. § 321(g), or that constitute a health claim that is not authorized by 21 C.F.R. §§ 101.72-101.83 or by a letter of enforcement discretion from FDA. The report shall include the specific results of the labeling expert's review, including references to product names and regulations addressed in the process of conducting the review. The report shall also include copies of all materials reviewed other than FDA regulations. The labeling expert shall submit his/her report to FDA at the address in Paragraph 16; and

f. FDA notifies Defendant in writing that Defendant appears to be in compliance with the requirements set forth in subparagraphs 5(a)-(e). In no circumstance shall FDA's silence be construed as a substitute for written notification.

7. Upon entry of this Decree, Defendant and each and all of his directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing any of the following acts:

a. introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved pursuant to 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i); or

b. introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

8. Within three months of receiving the written notification from FDA referred to in Paragraph 5(f), Defendant shall submit to FDA a certification of compliance, signed by the expert, stating that the expert: (a) has personally reviewed all of Defendant's product labels, labeling, promotional materials, and internet websites; and (b) personally certifies that the product labels, labeling, promotional materials, and internet websites strictly comply with the requirements of the Act and its regulations and do not include claims that the products cure, mitigate, treat, prevent and/or reduce the risk of disease, and/or claims that the products are intended to affect the structure or any function of the human body, and/or constitute health claims that are not authorized by 21 C.F.R. §§ 101.72-101.83 or by a letter of enforcement discretion from FDA. Thereafter, Defendant shall submit the expert's certifications of compliance every three (3) months for a period of two (2) years.

9. If the expert reports any violations of the Act, Defendant shall, within seven (7) calendar days of receipt of the report, correct those deviations, unless FDA notifies Defendant in writing that a shorter time period is necessary.

10. Within ten (10) calendar days of FDA's request for any labels, labeling, promotional materials, and/or downloaded copies (on CD-Rom) of any internet websites owned and controlled by or related to Defendant, Defendant shall submit a copy of the requested materials to FDA at the address specified in paragraph 16.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, a review of Defendant's products, product labels, labeling, promotional

materials, or websites owned or controlled by or related to Defendant, a report prepared by Defendant's expert, or any other information, that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, and/or this Decree, FDA may, as and when it deems necessary, direct Defendant, in writing, to take one or more of the following actions:

a. Cease manufacturing, processing, packing, labeling, holding, promoting, and/or distributing any article(s);

b. Submit additional reports or information to FDA;

c. Pay liquidated damages as provided in Paragraph 17 below;

d. Recall any article(s) at Defendant's expense; or

e. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendant and his products into compliance with the Act, applicable regulations, and/or this Decree.

12. Any cessation of operations as described above shall continue until FDA notifies Defendant in writing that Defendant appears to be in compliance with the Act and the requirements of this Decree, and that Defendant may resume operations.

13. Duly authorized representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendant's facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted prompt access to buildings, equipment, in-process and finished materials, containers, labeling and other materials therein; to take photographs and make video recordings; to take samples of Defendant's finished and unfinished materials and products, containers, labels,

labeling, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, promoting, holding, and distribution of any and all Defendant's products in order to ensure continuing compliance with the terms of this Decree. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

14. Defendant shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendant's compliance with this Decree. For the purposes of this Decree, inspections include FDA's review and analysis of Defendant's claims for his products in the product labels, labeling, promotional materials, and any and all websites owned or controlled by or related to Defendant. The costs of such inspections shall be borne by Defendant at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.50 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

15. Within ten (10) calendar days after the entry of this Decree, Defendant shall: (1) provide a copy of this Decree, by personal service or certified mail (restricted delivery, return

receipt requested), to each and all of his suppliers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including "doing business as" entities) (hereafter collectively referred to as "associated persons"), and (2) post the Decree on all websites under Defendant's control. Within thirty-five (35) calendar days of the date of entry of this Decree, Defendant shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all associated persons who have received a copy of this Decree and the manner of notification. In the event that Defendant becomes associated, at any time after the entry of this Decree, with new associated persons, Defendant shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Decree to each such associated person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

16. Defendant shall notify FDA, in writing, at the address specified in Paragraph 16, at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in the corporate structure of Alternative Health & Herbs Remedies or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendant shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendant shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

17. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, Seattle District Office, United States Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington, 98021-4421.

18. If Defendant fails to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, upon receipt of a letter from FDA, Defendant shall pay to the United States of America: a sum of one thousand dollars ($1000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree, and an additional sum equal to twice the retail value of each shipment of an unapproved or misbranded drug in liquidated damages for each such unlawful shipment. For the purposes of this paragraph, a "violation" is defined as each time Defendant introduces or delivers for introduction into interstate commerce any product that is accompanied by (on the product's label, labeling, promotional materials, websites owned or controlled by or related to Defendant, or in any other media) a claim(s) that causes the product to be a drug within the meaning of the Act, unless the product is an approved new drug.

19. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendant shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

20. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be

based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

21. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED:

Dated this 20th day of Sept., 2012.

UNITED STATES DISTRICT JUDGE